



# **CDC post-authorization/post-licensure safety monitoring of COVID-19 vaccines**

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**Vaccine Safety Team**

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# Disclaimer

- The findings and conclusions in this presentation are those of the author and do not necessarily represent the official position of CDC



# Background

- U.S. government has a responsibility for public safety with respect to vaccines
  - Monitoring is independent from manufacturers and covers all vaccines
  - USG maintains the largest, most robust, and most sophisticated safety monitoring systems available in the United States
  - USG agencies collaborate on monitoring

## Background (cont.)

- CDC's Advisory Committee on Immunization Practices (ACIP) has established a COVID-19 Vaccine Safety Technical Sub-Group
  - Advise CDC and other federal partners on planning and preparation for post-authorization/post-licensure safety monitoring of COVID-19 vaccines
  - Independently review and evaluate safety data
- Post-authorization/post-licensure safety data on COVID-19 vaccines will be regularly presented at public ACIP meetings

# Topics

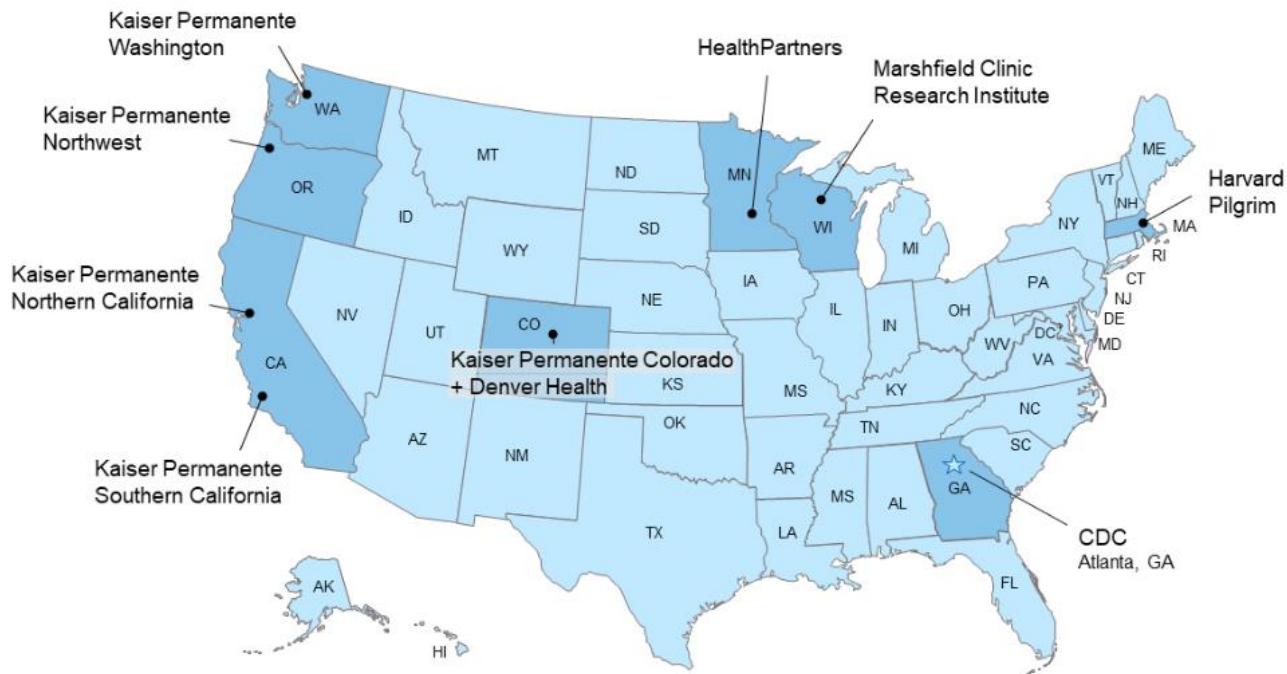
- Updates on Vaccine Safety Datalink (VSD) monitoring and the Clinical Immunization Safety Assessment (CISA) Project clinical consult service
- Vaccine Adverse Event Reporting System (VAERS)
  - Healthcare professionals' role in reporting adverse events
- **v-safe** smartphone-based active surveillance
  - Healthcare professionals' role in facilitating patient enrollment into **v-safe**

# Vaccine Safety Datalink (VSD)



# VSD

Vaccine  
Safety  
Datalink



9 participating integrated healthcare organizations

Data on over 12 million persons per year

# VSD planned monitoring and evaluation for COVID-19 vaccine safety

- Near real-time sequential monitoring (Rapid Cycle Analysis [RCA])
- Monitoring for vaccine-mediated enhanced disease (VMED)
- Studies to evaluate COVID-19 vaccine safety during pregnancy, including fetal death and infant outcomes
- Tree-temporal scan data mining
- Projects to assess:
  - Changes in healthcare utilization during COVID-19 and impact on AE monitoring
  - Utility of smartphone technology to enhance vaccine safety monitoring
  - Multisystem inflammatory syndrome (MIS-C and MIS-A) as vaccine AEs
  - Safety in an expanded underserved VSD population
  - Knowledge, attitudes, beliefs around acceptance/refusal of COVID-19 vaccination



# Preliminary list of VSD pre-specified outcomes for RCA

- Acute disseminated encephalomyelitis (ADEM)
- Acute myocardial infarction (AMI)
- Anaphylaxis
- Acute respiratory distress syndrome (ARDS)
- Arthritis and arthralgia / joint pain
- Convulsions / seizures
- Disseminated intravascular coagulation (DIC)
- Encephalitis / myelitis / encephalomyelitis / meningoencephalitis / meningitis / encephalopathy (not ADEM or TM)
- Guillain-Barré syndrome (GBS)
- Immune thrombocytopenia (ITP)
- Kawasaki disease (KD)
- Multisystem Inflammatory Syndrome (MIS-C and MIS-A)
- Myocarditis / pericarditis
- Narcolepsy / cataplexy
- Stroke – hemorrhagic and ischemic
- Transverse myelitis (TM)
- Venous thromboembolism (VTE)

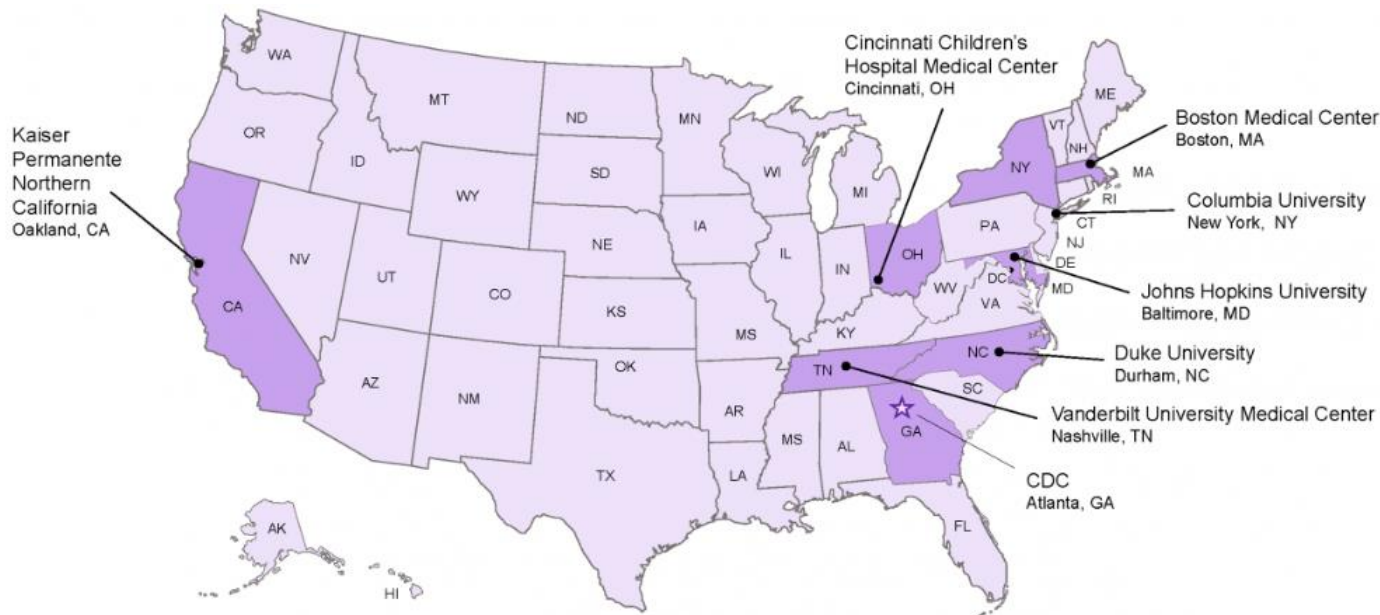
# **Clinical Immunization Safety Assessment (CISA) Project**



# CISA

## Clinical Immunization Safety Assessment (CISA) Project

7 participating medical  
research centers with  
vaccine safety experts



- clinical consult services<sup>†</sup>
- clinical research

<sup>†</sup>More information about clinical consults available at  
<http://www.cdc.gov/vaccinesafety/Activities/CISA.html>

# CISA Project consult service for COVID-19 vaccine safety

- Supports U.S. healthcare providers and health departments on complex clinical vaccine safety questions
- Assists with evaluations of patients with adverse events after COVID-19 vaccine or in making clinical decisions about administering COVID-19 vaccine to a person who may be at increased risk for an adverse event
  - Advice from CDC and the CISA Project is meant to assist in decision-making, rather than provide direct patient management
- Available to U.S. healthcare providers and health departments by contacting CDC-INFO\*

\*<https://www.cdc.gov/cdc-info/index.html>

# **Vaccine Adverse Event Reporting System (VAERS)**



# VAERS

## Vaccine Adverse Event Reporting System

Co-managed by  
CDC and FDA

<http://vaers.hhs.gov>

**VAERS** Vaccine Adverse Event Reporting System  
[www.vaers.hhs.gov](http://www.vaers.hhs.gov)

About VAERS

Report an Adverse Event

VAERS Data

Resources

Submit Follow-Up Information

Have you had a reaction following a vaccination?

1. Contact your healthcare provider.
2. Report an Adverse Event using the VAERS online form or the new downloadable PDF. *New!*

**Important:** If you are experiencing a medical emergency, seek immediate assistance from a healthcare provider or call 9-1-1. CDC and FDA do not provide individual medical treatment, advice, or diagnosis. If you need individual medical or health care advice, consult a qualified healthcare provider.

¿Ha tenido una reacción después de recibir una vacuna?

1. Contacte a su proveedor de salud.
2. Reporte una reacción adversa utilizando el formulario de VAERS en línea o la nueva versión PDF descargable. *Nuevo!*



What is VAERS?



REPORT AN ADVERSE EVENT

Report significant adverse events after vaccination.



SEARCH VAERS DATA

Download VAERS Data and search the CDC WONDER database.



REVIEW RESOURCES

Find materials, publications, learning tools, and other resources.



SUBMIT FOLLOW-UP INFORMATION

Upload additional information related to VAERS reports.

# VAERS is the nation's frontline system for monitoring vaccine safety

# Vaccine Adverse Event Reporting System (VAERS)

## Strengths

- National data
- Accepts reports from anyone
- Rapidly detects safety signals
- Can detect rare adverse events
- Data available to public

## Limitations

- Reporting bias
- Inconsistent data quality and completeness
- Lack of unvaccinated comparison group
- Generally cannot assess causality

- VAERS accepts all reports from all reporters without making judgments on causality or clinical seriousness of the event
- As a hypothesis generating system, VAERS identifies potential vaccine safety concerns that can be studied in more robust data systems

# Approaches to analyzing VAERS data

- Traditional methods
  - Clinical review of individual reports
  - Aggregate report review (automated data), e.g., case counts, frequencies of adverse event coding terms, reporting rates, reporting trends over time
- Statistical data mining methods
  - Detects disproportional reporting of specific vaccine-adverse event combinations in VAERS database



# Preliminary list of VAERS AEs of special interest\*

- COVID-19 disease
- Death
- Vaccination during pregnancy and adverse pregnancy outcomes
- Guillain-Barré syndrome (GBS)
- Other clinically serious neurologic AEs (group AE)
  - Acute disseminated encephalomyelitis (ADEM)
  - Transverse myelitis (TM)
  - Multiple sclerosis (MS)
  - Optic neuritis (ON)
  - Chronic inflammatory demyelinating polyneuropathy (CIDP)
  - Encephalitis
  - Myelitis
  - Encephalomyelitis
  - Meningoencephalitis
  - Meningitis
  - Encephalopathy
  - Ataxia
- Seizures / convulsions
- Stroke
- Narcolepsy / cataplexy
- Autoimmune disease
- Anaphylaxis
- Non-anaphylactic allergic reactions
- Acute myocardial infarction
- Myocarditis / pericarditis
- Thrombocytopenia
- Disseminated intravascular coagulation (DIC)
- Venous thromboembolism (VTE)
- Arthritis and arthralgia (not osteoarthritis or traumatic arthritis)
- Kawasaki disease
- Multisystem Inflammatory Syndrome (MIS-C, MIS-A)
- Acute respiratory distress syndrome (ARDS)

\*VAERS reports of AEs of special interest in blue will be clinically reviewed by CDC scientists

# Healthcare professionals' (HCP) role in VAERS reporting

- HCPs have been CDC's longstanding partners for reporting vaccine adverse events (AEs) to VAERS
  - VAERS depends on HCPs to identify and report suspected AEs, even if they aren't sure if a vaccine caused an AE
- HIPAA permits reporting of vaccine AEs and medical documentation (e.g., medical records) to VAERS for public health purposes
- HCP participation in VAERS reporting will enable public health officials to have accurate and timely information on the safety of COVID-19 vaccines
- Specific guidance on VAERS reporting for vaccines authorized for use under Emergency Use Authorization (EUA) will be forthcoming

Have you had a reaction following a vaccination?

1. Contact your healthcare provider.
2. [Report an Adverse Event](#) using the VAERS online form or the new downloadable PDF. *New!*

**Important:** If you are experiencing a medical emergency, seek immediate assistance from a healthcare provider or call 9-1-1. CDC and FDA do not provide individual medical treatment, advice, or diagnosis. If you need individual medical or health care advice, consult a qualified healthcare provider.

¿Ha tenido una reacción después de recibir una vacuna?

1. Contacte a su proveedor de salud.
2. [Reporte una reacción adversa](#) utilizando el formulario de VAERS en línea o la nueva versión PDF descargable. *Nuevo!*



What is VAERS?



REPORT AN ADVERSE EVENT

Review reporting requirements and submit reports.



SEARCH VAERS DATA

Download VAERS Data and search the CDC WONDER database.



REVIEW RESOURCES

Find materials, publications, learning tools, and other resources.



SUBMIT FOLLOW-UP INFORMATION

Upload additional information related to VAERS reports.

## VAERS Home

VAERS Home

About VAERS

Report an Adverse Event

Report Online

Report Using a PDF Form

VAERS Data

Resources

Submit Follow-Up Information

Frequently Asked Questions

Contact Us

Privacy

[Home](#) / [Report an Adverse Event](#)

[/ en Español](#)

## Report an Adverse Event to VAERS

VAERS is a passive reporting system, meaning it relies on individuals to send in reports of their experiences. Anyone can submit a report to VAERS, including parents and patients.

Healthcare providers are **required by law** to report to VAERS:

- Any adverse event listed in the [VAERS Table of Reportable Events Following Vaccination](#) that occurs within the specified time period after vaccinations
- An adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine

Healthcare providers are strongly **encouraged** to report to VAERS:

- Any adverse event that occurs after the administration of a vaccine licensed in the United States, whether it is or is not clear that a vaccine caused the adverse event
- Vaccine administration errors

Vaccine manufacturers are required to report to VAERS all adverse events that come to their attention.

Online reporting is strongly encouraged. Please report clinically important adverse events that occur after vaccination of adults and children, even if you are not sure whether the vaccine caused the adverse event.

The Vaccine Adverse Event Reporting System (VAERS) accepts all reports, including reports of vaccination errors. [Guidance on reporting vaccination errors](#) is available if you have additional questions.

**Knowingly filing a false VAERS report is a violation of Federal law (18 U.S. Code § 1001) punishable by fine and imprisonment.**





About VAERS

Report an Adverse Event

VAERS Data



Resources



Submit Follow-Up Information

## Completion Status

☐ Patient Information

☐ Reporter Information

☐ Facility Information

☐ Vaccine Information

☐ Additional Information

VAERS

Patient Information

Reporter Information

Facility Information

Vaccine Information

Additional Information

[Click to preview VAERS form](#)

## Report an Adverse Event - Patient Information

[Instructions](#) | [en Español](#)

**Note:** Fields marked with an \* are essential and should be completed.

### Item 1 ?

Patient first name:

Patient last name:

Street address:

City:

State:

Select State

County:

Zip code:

Phone:

Email:

### Item 2 ?

\* Date of birth ☒ mm/dd/yyyy or ☐ mm/yyyy



\* Sex:

☐ Male ☐ Female ☐ Unknown



### Item 4 ?

\* Date of vaccination ☒ mm/dd/yyyy or ☐ mm/yyyy



Time:

☐ AM ☐ PM

Item 27 ?

U.S. Military/Department of Defense status at the time of vaccination:

- ☐ Active Duty
- ☐ Reserve
- ☐ National Guard
- ☐ Beneficiary
- ☐ Other Military Status:

Item 28 ?

Vaccinated at Military/DoD site:

- ☐ Yes
- ☐ No

**Warning:** Knowingly filing a false VAERS report with the intent to mislead the Department of Health and Human Services is a violation of Federal law (18 U.S. Code § 1001) punishable by fine and imprisonment.

Prev

Submit



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[USA.gov](#) | [Centers for Disease Control and Prevention](#) | [Food and Drug Administration](#) | [U.S. Department of Health & Human Services](#)

VAERS is co-sponsored by the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA), agencies of the U.S. Department of Health and Human Services (HHS).



# How to report to VAERS



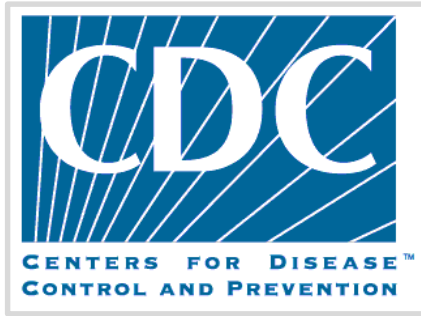
<https://www.youtube.com/watch?v=sbCWhcQADFE>







- **v-safe** is a new smart-phone based active surveillance program for COVID-19 vaccine safety
  - Uses text messaging to initiate web-based survey monitoring
  - Conducts electronic health checks on vaccine recipients
    - Daily for first week post-vaccination; weekly thereafter until 6 weeks post-vaccination
    - Additional health checks at 3, 6, and 12 months post-vaccination
  - Includes active telephone follow-up through the VAERS program with vaccine recipients reporting a clinically important event during any **v-safe** health check
    - A VAERS report will be taken during telephone follow-up, if appropriate
  - Captures information on pregnancy status and enables follow-up on pregnant women



1. Text message check-in or email from CDC  
(daily 1<sup>st</sup> week post-vaccination and weekly  
thereafter until 6 weeks post-vaccination)

Vaccine recipient completes web survey



This Photo by Unknown Author is licensed under CC BY-SA

**Vaccine recipient**

2. Clinically  
important  
event(s)  
reported

- ✓ Missed work
- ✓ Unable to do normal daily activities
- ✓ Received medical care

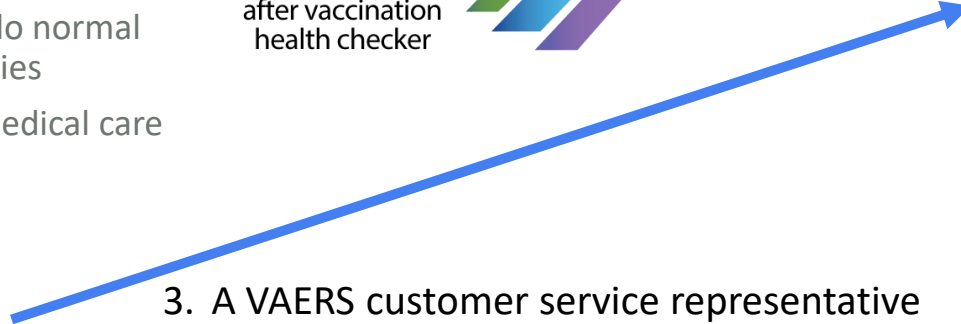


**VAERS call center**



This Photo by Unknown Author is licensed under CC BY-SA

**v-safe**  
after vaccination  
health checker



3. A VAERS customer service representative  
conducts active telephone follow-up on a  
clinically important event and completes a  
VAERS report if appropriate





- **v-safe** will allow estimation of:
  - Rates of local and systemic reactogenicity
  - Rates of clinically important adverse events following COVID-19 vaccination and symptoms and conditions associated with these adverse events

- Healthcare professionals (HCPs) will play an important role in **v-safe** enrollment
- CDC asks that:
  - HCPs provide a one-page **information sheet**\* to patients at vaccination →
  - HCPs counsel patients on the importance of enrolling in **v-safe**
- CDC will provide information on how to briefly counsel patients on **v-safe**



Log on with your phone's browser  
[xxxx.cdc.gov](https://xxxx.cdc.gov)  
OR

Scan the code  
with your  
phone's camera



**Get vaccinated. Get your smartphone. Get started with v-safe.**

**V-safe** is a new smartphone-based tool that checks on you after your COVID-19 vaccination. Getting vaccinated is part of getting your life back to normal. **V-safe** personalized health check-ins let you share your vaccination experience and let us know if you have any side effects. Your participation will help keep COVID-19 vaccines safe — for you and for everyone.

**What is v-safe?**  
**V-safe** is a new smartphone-based tool that uses text messaging and web surveys to check in with you for side effects after a COVID-19 shot. **V-safe** also provides 2<sup>nd</sup> dose reminders if needed and live telephone follow up by CDC if you report a medically significant adverse event, so we can better understand the symptoms you might be experiencing.

- Easy to use with your smartphone
- Convenient health check-ins and 2<sup>nd</sup> dose reminders
- Confidential and secure

\*CDC will create an electronic version of the **v-safe** information sheet for printing

# Summary

# Summary

- The Vaccine Safety Datalink (VSD), Clinical Immunization Safety Assessment (CISA) Project, and other planned projects are key components of COVID-19 vaccine safety monitoring and adverse event assessment
- VAERS is the U.S. frontline vaccine safety monitoring system
  - VAERS traditionally has provided the initial data on the safety profile of new vaccines when they are introduced for use in the population
  - Healthcare providers (HCPs) can play an important role in identifying and reporting potential AEs to VAERS: **HCPs are partners in safety monitoring**
- **v-safe** is a new smart-phone based active surveillance program
  - HCPs can play an important role in helping CDC enroll patients in **v-safe** at the time of vaccination: **HCPs are partners in safety monitoring**

**Questions?**